UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,346	01/14/2004	Heinrich Kladders	01-1447	3492

28501 7590 10/13/2009

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM USA CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
10/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/757,346	KLADDERS ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the request for continued examination submitted on 9/16/2009. No claims were amended, added or cancelled. Currently, claims 1-10 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5,947,118) in view of Datta et al. (US 5,871,010) and further in view of Bartels et al. (US 5,472,143).

As to claims 1 and 5, Hochrainer et al. disclose an inhaler for the administration of a pharmaceutical composition comprising a mouthpiece (12), an air channel opening into the mouthpiece and a chamber (9) with an air inlet channel wherein the inhaler is capable of receiving a capsule with a composition (see Figure 6). Hochrainer et al. does not disclose at least part of the inner surface of the mouthpiece and/or of the air channel and/or optionally the chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 microns. However, Datta et al. teach an inhaler apparatus with a modified surface for enhanced release of dry powders. Datta et al. disclose the surface of the substrate and the mouthpiece as having elevations and depressions with a depth of one micron to about 2.5 microns (column 2, lines 15-

44), which meets the claimed range of 0.1 to 100 microns. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. with the depressions taught by Datta et al. in order to decrease the area of contact between the selected medicaments so that medicament particles do not stick to the inside surface of the mouthpiece. In addition, the only difference between the depressions of Datta et al. and the instant application is the shape (i.e., sloped and/or tapered parabolic-shaped versus parallel grooves). Absent a critical teaching and/or a showing of unexpected results from making the depressions sloped/tapered shaped, Examiner contends it is an obvious design consideration to one of ordinary skill in the art to make the depressions sloped or tapered as a matter of manufacturing preference because sloped/tapered is a well known shape. Furthermore, because the grooves of Datta et al. are provided to minimize the area of contact in order to maximize the release of medicament (column 2, lines 25-30 and column 7, lines 55-60), it appears as though the modified device would perform equally well with sloped/tapered depressions as opposed to parallel grooves. See also *In re Dailey*, 357 F.2nd 669, 149 USPQ 47 (CCPA 1966), in which the court upheld that changes in shape without a change in function do not patentably distinguish a claimed invention over the prior art. To the extent that the modified Hochrainer and Datta et al. reference is silent as to the process for forming the elevations/depressions Bartels et al. disclose an atomizing nozzle for use in an inhaler in which the depressions forming the nozzle outlets are formed from well-known microforming techniques including chemical etching, laser, photo-resist, or other engraving techniques (column 4, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used chemical etching (a microtechnology and subtractive

treatment), for example, to produce the depressions in the modified device of Hochrainer et al. and Datta et el. in order to produce readily reproducible and accurate depressions in the mouthpiece on a micro-scale.

As for claim 2, Datta et al. is silent as to the percentage of the interior surfaces having depressions. However, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have used microtechnology to produce depressions over at least 20% of the inner surfaces in order to deliver a maximum amount of medicament to the user without having the particles stick to the inside surfaces of the inhaler.

As for claim 3, Datta et al. disclose the elevations and depressions are separated by spacings of 2 microns, which reads inside the range from 0.1 to 200 microns.

As for claim 4, Datta et al. has taught an inhaler with inner surfaces being made with polycarbonate (column 7, line 65), for example, which is one of the claimed materials.

As for claims 6 and 7, Hochrainer et al. inherently disclose a Bernoulli inhaler. In addition, the applicant has admitted that Bernoulli inhalers are prior art (paragraph 3, lines 4-7). Hochrainer et al. disclose the inhaler comprising a capsule chamber (9), which is connected to the air channel opening in the mouthpiece.

In regards to claims 9 and 10, Hochrainer et al. disclose the inhaler as having a cutting device, which is fitted with at least two sharp spikes, the spikes are capable of being inserted through openings into the capsule chamber (column 3, lines 5-9). Hochrainer et al. continue to disclose an inhaler comprising a cup-shaped lower part 6 open at the top, a plate (8) that covers the opening of the lower part (6) and perpendicularly to which is formed the capsule chamber, a button (10) movable counter to a spring on the capsule chamber, comprising two sharp spikes for

opening the capsule, an upper part (13) with the mouthpiece (12) and the air channel which connects the mouthpiece (12) to the capsule chamber (9) so as to be able to convey a powder or liquid or aerosol, and a lid, these elements being joined together by a common hinge element such that they can be moved back and forth relative to one another (column 3, lines 15-18).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. and Datta et al. and Bartels et al. and further in view of Kladders (US 4,889,114). The modified Hochrainer et al. reference has disclosed everything except the capsule chamber as having a diameter 1.1 to 2.5 times the capsule diameter and a length 1.02 to 2 times the length of the capsule. However, Hochrainer et al. has taught that the capsule chamber needs to have a diameter large enough to hold the capsule (column 1, lines 19-21). In addition, Kladders discloses a similar powder inhaler with a capsule chamber (6) with a diameter 1.1 to 2.5 times the capsule diameter and a length 1.03 to 2 times the length of the capsule (column 2, lines 10-19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Hochrainer et al., Datta et al., and Bartels et al. with the capsule chamber diameter and length as taught by Kladders so that the capsule fits in the chamber in order to be more effective during delivery for inhalation.

Response to Arguments

Applicant's arguments filed 9/16/2009 have been fully considered but they are not persuasive.

Applicant submits no new arguments (i.e., impermissible hindsight, Datta teaching away from sloped indentations because of its teaching of minimizing the surface contact area, and "surprising results" from the shape of the indentations) from previous responses and therefore examiner does not address these arguments again here. Please see the Advisory Action of 3/27/09 and the Final Rejection of 12/16/08 for the response to these arguments.

Response to Amendment

The declaration under 37 CFR 1.132 filed 9/16/2009 is insufficient to overcome the rejection of claims 1-10 based upon Hochrainer et al., Datta et al., Bartels et al., and Kladders as set forth in the last Office action because it fails to set forth conclusions that are supported by clear factual evidence.

As discussed in great detail in previous actions, Datta et al. does not disclose sloped/tapered elevations/depressions, but changing the shape of the perpendicular depressions of Datta et al. to sloped depressions is considered an obvious design consideration to one of ordinary skill in the art as a mere change in shape without a significant change in function. A change in shape does not patentably distinguish an invention over the prior art when the change in shape does not significantly change the function of the prior art (here, depending on the size of the depressions, the surface area will still be decreased/minimized from a flat surface as required by Datta et al.). Such a modification involves substitution of a well known method/shape into a well known device to yield predictable results that do not patentably distinguish an invention over the prior art. Examiner has cited several references that teach producing sloped/tapered depressions using microfabricaiton techniques as more evidence that such a change in shape was

both possible and obvious. See specifically Benson et al. figures 18a and 18b, which shows sloped surfaces in a repeating "egg-carton" pattern on a substrate.

Furthermore, as discussed in previous Actions, merely stating that the shape of the depressions is "surprising" or "optimal" is not given enough patentable weight to overcome the rejection without supporting factual evidence supporting this claim. Additionally, examiner notes that the term "surprisingly" as cited in the remarks and declaration is only used regarding the success of elevations/depressions in powder inhalers in general, and the prior art clearly teaches use of elevations/depressions in powder inhalers. Furthermore, optimalization within a range of known possibilities (i.e., known shapes of microfabricated depressions) is not considered to patentably distinguish an invention over the prior art.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2008/0074743 (Figure 18b), US 5750241 (columns 2-3), and US 5317938 (column 4) are cited to show that sloped/tapered shapes were well known and commonly used in micofabrication techniques at the time the invention was made.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771